REMARKS

After entry of this amendment, claims 1, 3, 4, 6-8, 11-13, and 29 are pending. Claims 2, 5, 9-10, and 14-27 have been cancelled without prejudice. Applicant reserves the right to pursue these claims in a continuation application. Claims 1, 6, 12, and 13 have been amended, and new claim 29 has been added. The subject matter of claim 5 has been incorporated into independent claim 1, and claims 6, 12, and 13 have been amended to conform with the amendment to claim 1. The amendments to claims 1, 6, 12, and 13 and new claim 29 are fully supported by the originally-filed specification and original claims of the parent application and do not introduce new matter. Reconsideration of the present application and entry of the above amendments in view of the following remarks are respectfully requested.

I. DOUBLE PATENTING

Claims 1, 3, 4, 6-8, and 11-13 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,652,581. To expedite prosecution and while not agreeing with this rejection, Applicant is submitting a Terminal Disclaimer Under 37 C.F.R. § 1.321(c), with the necessary fee, in connection with U.S. Patent No. 6,652,581 to overcome the double patenting rejection. Common ownership of the present application and United States Patent No. 6,652,581 is established in the Terminal Disclaimer. Such Terminal Disclaimer is believed to obviate this rejection.

II. 35 U.S.C. § 103

A. Claim 12 is Patentable over U.S. Patent No. 5,205,921 to Shirkanzadeh

Claim 12 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,205,921 to Shirkanzadeh ("Shirkanzadeh"). Applicant respectfully disagrees.

Claim 12 depends from claim 1 which recites a "method of making a stent . . . wherein the stent comprises a sidewall having a plurality of openings therein and wherein at least a part of the sidewall comprises a surface formed from a porous material having a plurality of voids therein to release at least one biologically active agent therefrom, the method comprising loading the porous material with the biologically active agent . . . wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body." Claim 12 further recites that the "biologically active agent is loaded immediately before implantation of the stent."

Shirkanzadeh teaches a process for depositing ceramic compounds such as calcium phosphate or aluminum oxide, onto conductive substrates, such as stainless steel, titanium, or alloy implants (column 1, lines 6-12; column 1, lines 64 to column 2, line 53) to improve the biocompatibility of the implant by promoting bone ingrowth.

In contrast to the presently claimed invention, Shirkanzadeh does not disclose or suggest a method of making a stent as presently claimed. Shirkanzadeh does not even disclose or suggest the use of a stent or any medical device having a sidewall with a plurality of openings therein.

In addition, Shirkanzadeh does not teach or suggest a method of depositing a biologically active agent such as a drug *into* the voids of the porous material of a sidewall of a stent. Specifically, Shirkanzadeh is completely silent that its phosphate or oxide is actually deposited into the voids of the porous material as required by the present invention. Instead, Shirkanzadeh merely teaches a method of depositing ceramic compounds, such as calcium phosphate, *onto* the surface of a substrate so as to improve the effectiveness and biocompatibility of the implant (column 1, line 64 to column 2, line 2). In fact, Shirkanzadeh teaches that calcium phosphate is "precipitated as a dense, adherent film onto the cathode" rather than deposited into the voids of the device material as in the present invention (column 2, line 44).

Furthermore, Shirkanzadeh does not teach or suggest that the ceramic compounds may be released from the device upon implantation of the device into the body, as presently claimed. In fact, Shirkanzadeh teaches away from the present invention. Specifically, since the ceramic compounds in the coatings enhance the biocompatibility of the implant by promoting bone ingrowth (column 1, lines 15-19), Shirkanzadeh teaches that the ceramic compound coating remains on the implant as an "adherent film" and that "[a]dherent coatings" are formed (column 2, lines 38-46). Hence, Shirkanzadeh teaches that the components of its coating adheres to the device even when the device is implanted. In contrast, in the present invention components of the coating, *i.e.,* the biologically active agent, are released when the device is implanted. Thus, Shirkanzadeh teaches away from the claimed invention.

Therefore, Shirkanzadeh does not disclose or suggest the present invention since it fails to disclose or suggest a method of loading a biologically active agent into the voids of porous material of a sidewall of a stent and the subsequent release of such agent after implantation of the stent. Thus, Shirkanzadeh does not disclose or suggest, and in fact teaches away from, loading a porous material with a biologically active agent, wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body, as presently claimed.

With respect to claim 12, Shirkanzadeh also does not disclose or suggest that "biologically active agent is loaded immediately before implantation of the stent", as acknowledged by the Examiner in the Office Action on page 4.

Accordingly, it is believed that claim 12 (which depends from claim 1) is patentable over Shirkanzadeh. Thus, withdrawal of this rejection and allowance of claim 12 are respectfully requested.

For the reasons discussed above, it is believed that new claim 29 is also patentable over Shirkanzadeh.

B. Claims 1, 3, 4, 6-8, and 11-13 are Patentable over U.S. Patent No. 5,843,172 to Yan in view of Shirkanzadeh

Claims 1, 3, 4, 6-8, and 11-13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,843,172 to Yan ("Yan") in view of Shirkanzadeh. Applicants respectfully disagree.

As acknowledged by the Examiner, Yan does not disclose or suggest an electrodeposition method for loading a stent with a biologically active agent. (Office Action, page 5). In particular, Yan does not disclose or suggest a method comprising loading a porous material with a biologically active agent by: a) forming a solution or suspension of the biologically active agent; b) placing the stent into the solution or suspension; c) placing an electrode in the solution or suspension; d) applying an electric current to the stent and the electrode; and e) allowing at least some of the biologically active agent to be loaded into the voids" as recited in claim 1. Thus, it is believed that claim 1 and claims 3, 4, 6-8 and 11-13 depending therefrom are also patentable over Yan. Shirkanzadeh does not remedy the deficiencies of Yan.

For the reasons discussed above, it is believed that claim 1 and claims 3, 4, 6-8, and 11-13 depending therefrom are patentable over Shirkanzadeh. In particular, Shirkanzadeh does not disclose or suggest, and in fact teaches away from (as previously described), loading a porous material of a sidewall of a stent (or any medical device) with a biologically active agent, wherein at least a portion of the biologically active agent is releaseable from the stent or device upon insertion into the body, as presently claimed.

Moreover, one skilled in the art would not find motivation in the disclosures of Yan and Shirkanzadeh to combine the teachings of these references to obtain the present invention, particularly where Yan does not disclose or suggest the specific method of loading a stent with a biologically active agent as presently claimed and Shirkanzadeh does not disclose or suggest the use of a stent and in fact teaches away from loading a porous material of a stent (or any medical device) with a biologically active agent that is releasable from the stent or device.

Accordingly, it is believed that claim 1 and the claims depending therefrom are patentable over Yan and Shirkanzadeh, whether taken alone or in combination. Thus, withdrawal of this rejection and allowance of claims 1, 3, 4, 6-8, and 11-13 are respectfully requested.

For the reasons discussed above, it is believed that new claim 29 is also patentable over Yan and Shirkanzadeh, whether taken alone or in combination.

C. The Present Claims are Patentable over Yan in view of Shirkanzadeh and U.S. Patent No. 4,101,984 to MacGregor

Claims 14-19 and 27 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Yan in view of Shirkanzadeh as applied to claims 1-13 and further in view of U.S. Patent No. 4,101,984 to MacGregor ("MacGregor"). Applicant respectfully disagrees. However, to expedite prosecution, claims 14-19 and 27 have been canceled. The cancelation of claims 14-19 and 27 obviates this rejection.

III. CONCLUSION

In view of the above amendments and remarks, it is believed that the rejections have been overcome and that the present application is in condition for allowance. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,
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Enclosures